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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,798	04/10/2001	Takao Daicho	109146	8412

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,798

Applicant(s)

Daicho, T.

Examiner

Patricia Patten

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 18, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1651

DETAILED ACTION

Claims 1-7 are pending in the application and were presented for examination on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The Specification is objected to for the following informalities:

The Specification contains plants which are referred to by the Chinese name with Chinese characters. Further, these Chinese names for plants are not represented anywhere within the specification with any known botanical names. If there are botanical names which would correspond to the plants represented by Chinese characters, Applicants are asked to amend the Specification to change the Chinese characters to the known botanical names of the plants. If there is no known corresponding botanical names, then the Specification should be amended to omit this language as it is deemed to be confusing.

Art Unit: 1651

Election/Restriction

Applicant's election of the species Ginseng with traverse in Paper No. 6 is acknowledged. Applicants have traversed on the grounds that "the subject matter of all Species is sufficiently related that a thorough search for the subject matter of any one Species would necessarily encompass a search for the subject matter of the remaining Species," however, as it was stated in the Restriction Requirement (Paper No. 5): "Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case." Applicants have not provided any evidence on the record which would indicate that the species present in claims 6 and 7 are obvious variants of each other. Because applicant did not distinctly and specifically point out the particulars of why the species should be considered obvious variants or clearly admit that the species are obvious variants of each other, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Because Claim 7 is drawn to the non-elected species, and because the elected species has been rejected over the prior art, Claim 7 has been withdrawn from further consideration as being drawn to a non-elected invention.

Claims 1-6 have been presented for examination on the merits.

Art Unit: 1651

Claim Objections

Claim 6 is objected to because of the following informalities:

Claim 6 contains a limitation presented in the Chinese language, as well as pronunciations for each of the respective limitations. These limitations should be presented in the art recognized botanical terminology alone, rather than recitation of the Chinese phrase for the term (Please also see objection under the heading Specification, *supra*). Further, the pronunciations should not appear in the claims, as the pronunciations are not themselves patentable subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

Claim 2 recites 'wherein at least one member selected from isoflavones and isoflavone glycosides is comprised.' This statement is confusing in that the meets and bounds of the term 'is comprised' is not understood. It is suggested that the phrase be reworded to read: 'The health food product of claim 1 comprising at least one member selected from the group consisting of isoflavones and isoflavone glycosides' in order to avoid confusion.

Claim 5 recite 'crude drug.' This term is indefinite in that the term 'crude' is a subjective term which may have different meanings in the art. Thus the meets and bounds of the term are not clearly delineated. Further, the claim is indefinite in that it recites 'is admixed.' Is the drug admixed with the cholic acid? This is not clear with regard to the manner in which the claim is phrased. It is suggested that the preamble of the claim be reworded to read; 'The health food product according to claim 1 further comprising....' in order to avoid confusion.

Claim 6 recites the term 'the crude drug.' This phrase lacks antecedent basis in Claim 1, because claim 1 does not make reference to a crude drug. It is thought that these claims are intended to be dependant upon claim 5 which recites 'wherein at least one member selected from crude drugs is admixed.' Thus, if these claims were intended to have been dependant upon claim 5, it is suggested that the dependancies of this claim be changed to claim 5 rather than claim 1. Further, the claim refers to the plant species as 'crude drugs' however, it is not known what 'crude drug' the claim is actually specifying. Is a 'crude drug' a particular extract obtained from the plant; i.e., an alcoholic extract, an aqueous extract or an organic extract for example? Thus,

Art Unit: 1651

again the meets and bounds of the term 'crude drug' are not well defined, and thus the term is deemed indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Catalog (1997).

Claim 1 is drawn to a health food product comprising cholic acid. Cholic acid is a well known compound produced by the liver. Sigma for example, disclosed cholic acid on p.280 of their catalog. Thus, cholic acid was old and known in the art.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mach (US 4,487,766). Claims 1-5 are drawn to a health food composition comprising cholic acid, and further including an isoflavone, such as soy isoflavones, and a vitamin.

Mach (US 4,487,766) disclosed a 'breeding feed' which included ground soy beans (which inherently contained soy isoflavones), vitamins (A, D, E, K and B's) as well as cholic acid (Please see col.8, Table 1). With regard to 'crude drugs' being present in the composition; it is deemed

Art Unit: 1651

that a number of the constituents in the composition proposed by Mach would have been 'crude drugs.' For example, green alfalfa flour is deemed to be a 'crude drug' since alfalfa is known to inherently possess pharmacologically active phytochemicals such as saponins (anti-inflammatory agents)(as seen in Table 1), and is considered 'crude' because the saponins were not fully purified. Thus, the claims were anticipated over the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sha et al. (US 6,280,776) in view of Nakano et al. (JP 411046719A-English Abstract).

Claims 1 and 6 are drawn to a health food comprising cholic acid along with ginseng.

Sha et al. (US 6,280,776) disclosed Panax ginseng, present in health foods or feeds (Abstract) as being beneficial for liver disorders (col.2, lines 1-4 for example).

Art Unit: 1651

Nakano et al. (JP 411046719A-English Abstract) disclosed a nutritional supplement including cholic acid for absorption of lipids in infants (which would be beneficial in treating liver disorders via adsorbing lipids which a diseased liver could not support).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to be included in nutritional formulations for treating complications due to liver disorders. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore obvious.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

Art Unit: 1651

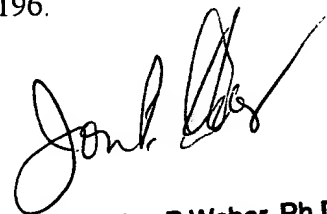
the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jon P. Weber", with a stylized flourish at the end.

Jon P. Weber, Ph.D.
Primary Examiner